US Army Medical Research and Materiel

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Recombinant Dengue Virus Vaccine: Nucleic Acid and Purified Particles

Features and advantages:

- **Envelope glycoprotein is easily produced in pure, chemically stable form**
- **Potential diagnostic tool**
- **Elicits high titers of neutralizing antibody**
- **Vaccine cannot infect the immunized host**

This invention provides a method for the production and purification of a recombinant protein for use as a vaccine against dengue virus. It also has potential as a diagnostic tool. The recombinant protein encompasses the complete dengue virus envelope glycoprotein and a portion of the carboxy-terminus of the membrane/ premembrane protein of dengue 2 virus. The recombinant protein can be expressed in the baculovirus system as a particle composed of multiple dengue envelope protein molecules. The protein particles are reactive with human convalescent sera, and with a panel of envelope-specific monoclonal antibodies that recognize native linear and conformational epitopes.

The purified recombinant protein particles provided protection in mice against lethal challenge with dengue 2 virus. Furthermore, nucleic acid sequences that generated the envelope particles may be used as a component of a nucleic acid vaccine against dengue virus (reference US Patent 6,514,501, February 2003).

Dengue viruses are human pathogens that pose a significant threat to world health. They are estimated to cause several hundred thousand cases of dengue fever, dengue hemorrhagic fever, and dengue shock syndrome annually. The four dengue serotype viruses are transmitted to man by the *Aedes* mosquito species. Dengue viruses are enveloped, and contain positive sense single-stranded RNA that encodes three structural and seven non-structural genes. Candidate vaccines include live attenuated virus strains, purified inactivated virus, recombinant and nucleic acid vaccines. The invention provides an alternative strategy to produce an immunogenic protein useful as a vaccine booster, or as a reagent for rapid diagnostic assays.

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